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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,364	04/25/2001	Frances Yen-Potin	GENSET.50CP2C	6570

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EXAMINER	
GOLDBERG, JEANINE ANNE	

ART UNIT	PAPER NUMBER
1634	10

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/842,364	Applicant(s) YEN-POTIN ET AL.	
	Examiner Jeanine A Goldberg	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 8/6/02 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, 15, drawn to nucleic acids, vectors, host cells, classified in class 536, subclass 23.1, 435/320.1 and 435/325.

II. Claims 5-6, drawn to transgenic animals, classified in class 800, subclass 8.

III. Claims 7-9, drawn to genotyping the identity of a biallelic marker, classified in class 435, subclass 6.

IV. Claims 10, 12-13, drawn to estimating the frequency of at least one allele, classified in class 702, subclass 27.

V. Claims 11, 14, drawn to methods of detecting an association between a genotype and a trait, classified in class 702, subclass 20.

VI. Claim 16, drawn to a polypeptide, classified in class 530, subclass 350.

VII. Claim 17, drawn to an antibody, classified in class 424, subclass 130.1.

2. The inventions are distinct, each from the other because of the following reasons:

A) The inventions of Groups I, II, VI, and VII are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group VI is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures

including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group VII is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The transgenic animal of Group II is a composition made up of structurally and functionally complex biological systems. Furthermore, the products of Groups I, II, III, and IV can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the antibody of Group VII can be used in immunoassay, the polypeptide of Group VI can be used to make fusion protein with an enzymatic function, while transgenic animals can be used to express different proteins other than AA4RP. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, II, III, and IV are patentably distinct from each other.

B) Group (II, VI, VII) and (III, IV, V) are patentable distinct inventions because the transgenic animal, the polypeptide and the antibody of Groups II, VI, VII is not relied upon in the methods of Group III, IV, and V. Instead Group III, IV, and V uses nucleic acids. Therefore, the inventions are novel and unobvious over one another.

C) The inventions of Group III, IV and V are patentably distinct methods because they each have different objectives, different uses, different reagents and different

method steps. The method of Group III is for genotyping the identity of a nucleotides at AA4RP. Alternatively, the method of Group IV is for a method of estimating the frequency of at least one allele in a population. The method of Group V is for a method of determining an association between an association between a genotype and a trait. Each of these methods requires different individuals, i.e. individuals, populations or trait specific populations. Therefore the methods are distinct over one another.

D) Inventions I and (III, IV, V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid may be used in materially different methods including purification methods, aptamer screening methods, antisense methods, hybridization methods, methods of detecting diseases.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

Restriction Requirement Applicable to All Groups:

4. The claims are drawn to multiple nucleic acid sequences and multiple biallelic markers. The change of a single nucleotide at the multiple biallelic markers may effect

the protein sequence. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. Further, even where the nucleic acid changes have no effect on protein structure or function, these sequences themselves represent allelic variations which have different diagnostic and therapeutic implications. A restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

The claims contains 8 individual, independent and distinct nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (November 19, 1996).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Applicant is required to select one of the biallelic markers. Each of the biallelic markers represents an independent and distinct invention. A search of a single biallelic marker is not coextensive of the other biallelic markers.

Should applicant traverse on the ground that the nucleic acids and biallelic markers are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Pauline Farrier, whose telephone number is (703) 305-3550.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg
September 24, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600